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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,340	02/17/2004	Neil S. Cutshall	60117-106	9233
22504 7590 08/05/2009 DAVIS WRIGHT TREMAINE, LLP/Seattle 1201 Third Avenue, Suite 2200 SEATTLE, WA 98101-3045				
EXAMINER				
DESAL, RITA J				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
08/05/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/781,340

**Applicant(s)**

CUTSHALL ET AL.

**Examiner**

Rita J. Desai

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30, 41-45, 47, 48, 50-53, 55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) 1-30, 43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41, 42, 45, 47, 48, 50-53, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/17/09 has been entered.

Claims 1-30, 43, 44, are withdrawn.

Claims 31-40, 46, 49, 54, 57-59, are cancelled.

Claims 41, 42, 45, 47, 48, 50-53, 55, 56 are pending.

Response to the arguments :-

The objections to the claims have been withdrawn, as applicants have amended the claim.

The rejection under 35 USC 112 of claims 41, 42, 45, 47, 48, 50-53, 55, 56, still stands changed to 112 new matter.

Applicants have amended the claims to limit the inflammation due to GRO- $\alpha$  and IL-8, however the specification has no description of what these inflammations are. As given earlier the definition of inflammation is very broad and inclusive of many many conditions. Applicants have also amended it to inflammation mediated atleast in part by IL-8 or GRO- $\alpha$ .

This raises new issues and new matter issues as the specification does not clearly describe which are the inflammation mediated by IL-8 or GRO-  $\alpha$ .

New Rejections

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41,42, 45, 47, 48, 50-53, 55, 56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 48 and 49 of U.S. Patent No. 6777432. Although the conflicting claims are not identical, they are not patentably distinct from each other because these claims are also drawn to the method of treating inflammatory disorders alleviated by inhibition of GRO.

Claims 41,42, 45, 47, 48, 50-53, 55, 56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7151112. Although the conflicting claims are not identical, they are not patentably distinct from

each other because the claims are drawn to the method of inhibiting IL-8 and GRO and mediate the disorders associated by it.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41,42, 45, 47, 48, 50-53, 55, 56 rejected under 35 U.S.C. 102(b) as being anticipated by KlebanovB.N.et.al.

Art Unit: 1625

CaplusAN1978:15765.

AB Thirteen pyridine carboxylic acid deriva. (I) were prepd. and tested for antiinflammatory, antipyretic, and analgesic effects in rats and mice. All compds. tested inhibited keolin- or formalin-induced swelling, and no relation existed between the position of the carboxyl group in the Ph residue and antiinflammatory effectiveness. Substitution of NH at X with C decreased antiinflammatory activity. Isonicotinic acid deriva. contg. a carbomethoxy group had the greatest antipyretic and analgesic activities. LD50 values were given for all compds.

AN 1978:15765 CAPLUS

DN 88:15765

TI Antiinflammatory activity of some new pyridine carboxylic acid derivatives

AU Klebanov, B. M.; Ryabukha, T. K.; Portnyagina, V. A.; Denilenko, V. P.; Get'man, G. A.

CS Kiev. Nauchno-Issled. Inst. Farmakol. Toksikol., Kiev, USSR

SG Fiziologicheski Aktivnye Veshchestva (1977), 9, 17-19

COEN: PAVOAI; 1988N, 9533-1153

DT Journal

LA Russian

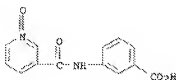
LT 62833-95-8

RI: BAC (Biological activity or effector, except adverse); BSU (Biological study, unclassified); THU (Therapeutic use); BIOL (Biological study); USES (Uses)

(pharmacol. of)

RN 62833-95-8 CAPLUS

CN Benzoic acid, 3-[[1-(1-oxido-3-pyridinyl)carbonyl]amino]- (9CI) (CA INDEX NAME)



The reference discloses the compound for the use as an antiinflammatory activity.

It reads on the compounds when R1 is R5 and R5 is H.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41,42, 45, 47, 48, 50-53, 55, 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been amended to now include mediated at least in part by IL-8 or GRO- $\alpha$ .

There is no description of what is included by this term.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/  
Primary Examiner, Art Unit 1625

July 30, 2009